

NOBAMED Paul Danz AG

NOBAFIX[®]-steril

REF 731112

Product Description, Intended use, Application

This fixation bandage with a width of 12 cm and a stretched length of 4 m is a rolled, lengthwise-elastic dressing retention bandage. Due to its weave, the bandage has a fine, smooth and tight structure. The elastic bandage is used to fix wound pads, especially over joints and body curves. As a damp bandage, NOBAFIX[®] is also used to shape and/or fix plaster splints and cast dressings. NOBAFIX[®]-steril is for single use.

Composition

Polyester

Contra-Indications

The product should not be used in the case of a known allergy against the material.

Incident reporting

According to MDR (EU) 2017/745, if serious incidents occur in relation to the device, they must be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

Normative and Regulative Requirements, Common Standards

Medical device according to the MDD 93/42/EEC and MDR (EU) 2017/745.

Sterilization of the product complies with DIN EN ISO 11135.

The product does not contain dangerous toxic substances according to REACH.

Packaging

Primary packaging:	paper-foil- packaging
Secondary packaging:	folding box made of cellulose

Tertiary packaging:

carton made of cellulose

Symbols used in labelling Explanations at <u>www.nobamed.com</u>



Marking on all packaging levels with CE and according to DIN EN ISO 15223-1 and ISO 20417.

Storage and Transport

To be stored in a dry and dust-free environment

Sterile device

Before using a sterile product, visually inspect the packaging to ensure that it is intact.

Single use device

Reusing a single use medical device can lead to microbiological danger. Reprocessing, for reuse can decrease the product's performance significantly.

Disposal

According to locally applicable legal regulations and standards of infection prophylaxis.